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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0568]

Draft Guidance for Industry and FDA Staff on Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA] is announcing the availability of the draft guidance for industry and FDA staff entitled "Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices." It was developed as a special control to support the reclassification of the vascular embolization device and the neurovascular embolization device from class 111 (premarket approval) into class II (special controls). The draft guidance is not final nor is it in effect at this time. We are also announcing the withdrawal of the 1994 draft guidance document entitled "Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3—Implant Model," dated September 12, 1994.

DATES: Submit written or electronic comments on the draft guidance by *[insert date 90 days after date* of *publication in the* **Federal Register].**

ADDRESSES: Submit written requests for single copies of the draft guidance on a 3.5" diskette to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, **1350** Piccard Dr., Rockville, MD 20850. Send

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two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to ***http://www.fda.gov/dockets/ecomments***. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Peter L. Hudson, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled "Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices."

On June 12, 1998, the Neurological Devices Panel (the Panel) considered the information in three submissions of safety and effectiveness under section 515(i) for the neurovascular embolization device, and recommended that this device be reclassified from class III into class II.

While the Panel's recommendation was specifically for the neurovascular embolization device, because of the similarity of the vascular (arterial) embolization device to the neurovascular (artificial) embolization device, with regard to its intended use, design, risks to health, and measures to mitigate the risks to health, FDA determined that the Panel reclassification recommendation for the neurovascular embolization device is relevant to the vascular embolization device.

We are withdrawing the guidance document entitled "Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3—Implant Model" because it contains outdated information. Archived copies of Center for Devices and Radiological Health (CDRH) guidance documents that have been withdrawn are available from the Division of Small Manufacturers, International, and Consumer Assistance (see **ADDRESSES).**

Elsewhere in this issue of the **Federal Register,** FDA is proposing to reclassify the vascular embolization device and the neurovascular embolization device into class II. The currently available guidance document entitled "Guidance for Neurological Embolization Devices" dated November 1, 2000, was revised as a draft class II special controls guidance document to support the reclassification of these device types. If finalized, the "Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices" will supersede the November 1, 2000, guidance document and will serve as the special control for these devices.

Following the effective date of any final reclassification rule based on this proposal, any firm submitting a premarket notification (510(k)) for a vascular embolization device or a neurovascular embolization device will need to address the issues covered in the special controls guidance document. However, the firm need only show that its device meets the recommendations of the guidance document or in some other way provides equivalent assurances of safety and effectiveness.

II. Significance of Guidance

This draft guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on vascular and

neurovascular embolization devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies fhe requirements of the applicable statute and regulations.

111. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB)under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (the PRA). The collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing 510(k) submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance document have been approved by OMB under the PRA, OMB control number 0910–0485.

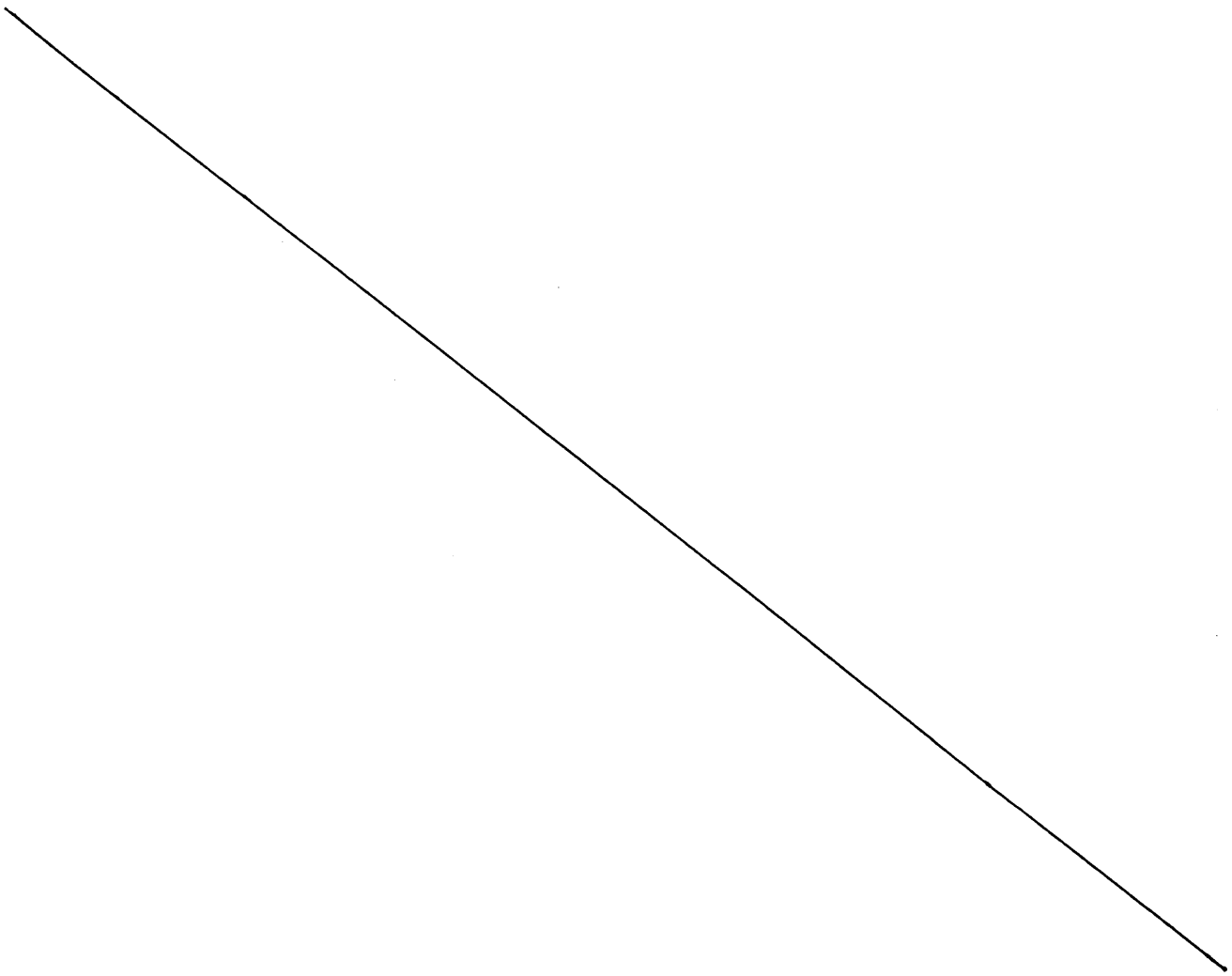
IV. Comments

You may submit to the Division of Dockets Management (see **ADDRESSES)** written or electronic comments on the draft guidance. You may submit a single copy of an electronic comment (see **ADDRESSES).** Submit two copies of any mailed comments, but individuals may submit one copy. You should identify your comment with the docket number found in brackets in the heading of this document. You may see any comments FDA receives in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

To receive a copy of the draft guidance by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1234) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance document may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** notices, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is avai1ab1e at *http://www.fda.gov/cdrh/guidance.htm1*.



Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets.*

Dated: 2/11/04
February 11, 2004.

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